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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,442	03/07/2000	Gopinathan K. Menon	680.0035USU	1007

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EXAMINER	
DI NOLA BARON, LILIANA	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/521,442	MENON, GOPINATHAN K.	
	Examiner	Art Unit	
	Liliana Di Nola-Baron	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 14-35* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 March 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The instant application has been withdrawn from issue. Prosecution on the merits is hereby reopened. An action on the merits is enclosed.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 21 and 24-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims lack written description under 35 U.S.C. 112, first paragraph, because the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to the broad genus encompassing PPAR stabilizers. Members of this genus are only described in the specification by general function. There is no description of any common structure and there is only a single species disclosed, that of perilla oil.

3. Claims 21 and 24-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising topically applying perilla oil, does not reasonably provide enablement for the claimed PPAR stabilizers. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention is directed to a method of providing an improvement in the esthetic appearance of the skin by reducing lipid synthesis and triglyceride synthesis in subcutaneous adipose tissue, comprising topically applying a PPAR stabilizer to the skin.

(2) The state of the prior art

The prior art (Kondo et al.) provides an external medicine for the skin comprising perilla oil and showing excellent amelioration against xerosis and dry skin.

(3) The relative skill of those in the art

The relative skill of those having a Ph.D. in the cosmetic art is high.

(4) The predictability or unpredictability of the art

The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results from the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by Applicant.

(5) The breadth of the claims

The method claims are very broad. No steps are recited in the claims.

(6) The amount of direction or guidance presented

The amount of direction and guidance provided by Applicant is limited to formulations comprising perilla oil. The artisan skilled in the art would not know how to make PPAR stabilizers other than perilla oil in order to practice the invention. There is no evidence in the specification that established correlation between the experiments and the claimed utility. Applicant's specification does not provide any direction or guidance about the nature of PPAR stabilizers to be used and the steps to be taken in order to make said PPAR stabilizers. Additionally, Applicant's specification does not provide any direction or guidance on how to achieve the claimed reduction of lipid and triglyceride synthesis in adipose tissue by topical application of the composition of the invention.

(7) The presence or absence of working examples

The working examples are limited to formulations comprising perillla oil.

(8) The quantity of experimentation necessary

The nature of PPAR stabilizers and their effect on the skin and adipose tissue, for which no correlation has been established, cannot be predicted a priori but must be determined from the case to case by painstaking experimental study in vivo. When the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine a possible effect of the compounds claimed in the instant application on the skin and lipid and triglyceride synthesis in adipose tissue.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 21, 24-26 and 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "Means" and method appear to be used interchangeably in the claims. As a result the metes and bounds of the claims aren't clear.

6. The means of claim 21 and 32 are unclear. If claim 21 recites the complete means required for providing an improvement, then it is unclear why the additional means in claim 32 are required to provide the improvement. The dependent claim contradicts the assertion of the base claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21-28 and 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Patent 7-187989 to Miyazaki et al.

The abstract of the Japanese patent discloses a cosmetic preparation for application to the skin comprising 1% of perilla extract to be used for whitening the skin and preventing sunburn. Thus, the abstract teaches a method comprising topically applying perilla oil to the skin. The reduction in oil production by sebaceous glands, lipid and triglyceride synthesis in adipose tissue, and amelioration of cellulite and acne claimed by Applicant are inherent to the method and composition disclosed by the prior art. Thus, the Japanese patent anticipates the claimed invention.

9. Claims 21-26 and 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Patent 8-119829 to Kondo et al.

The abstract of the Japanese patent discloses an external preparation for application to the skin comprising perilla oil to be used for ameliorating xerosis and dry skin. Thus, the abstract teaches a method comprising topically applying perilla oil to the skin. The reduction in oil production by sebaceous glands, lipid and triglyceride synthesis in adipose tissue, and amelioration of cellulite

and acne claimed by Applicant are inherent to the method and composition disclosed by the prior art. Thus, the Japanese patent anticipates the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent 7-187989 to Miyazaki et al.

The teachings of the abstract of the Japanese Patent have been summarized above. With respect to claim 29, the abstract is deficient in the sense, that it discloses a formulation comprising 1% of perilla oil. The amount of perilla oil disclosed by the patent is lower than the amount range claimed by Applicant. Applicant has not established the criticality of the amount range of PPAR stabilizer claimed and there is no comparable example in the specification to demonstrate that the claimed amount range of PPAR stabilizer provides some unusual and/or unexpected results. It appears to the examiner that the claimed amount range does nothing additional to the method of the invention, especially in view of the teachings of the prior art, that perilla oil is an effective agent in compositions topically applied to the skin.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of the Japanese Patent to device a method comprising topically applying a composition comprising perilla oil to the skin. The expected result would have been a successful method for improving the appearance of the skin. Because of the teachings of the Japanese Patent, that perilla oil is an effective agent when topically applied to the skin, one of ordinary skill in the art would have a reasonable expectation that the method claimed in the instant application would be successful at ameliorating the skin. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

12. Applicant's arguments filed on November 19, 2003 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 571-272-0592. The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 15, 2004

THURMAN K. PAGE
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